MAR 7 2006

Special 510(k) Summary
Albert Browne Ltd.
VERIFY® STEAM Value Indicators

K060103

1. SUBMITTED BY: Albert Browne Ltd.
Chancery House
190 Waterside Road
Hamilton Industrial Park
Leicester LE5 1QZ
United Kingdom

CONTACT PERSON: Richard Bancroft
Chancery House
190 Waterside Road
Hamilton Industrial Park
Leicester LE5 1QZ
United Kingdom

Telephone: 0116 276 8636

DATE PREPARED: January 11, 2006

2. DEVICE NAME: VERIFY® STEAM Value Indicators

CLASSIFICATION NAME: Physical/chemical sterilization process indicator

CLASSIFICATION STATUS: Physical/chemical process indicators are classified as Class II under Sterilization process indicator in 21 CFR 880.2800 (Product Code JOJ) by the General Hospital and Personal Use Devices Panel

3. PREDICATE DEVICE

- Modified Browne Packaging and Label Steam Process Indicator (K032801)

4. INTENDED USE

The VERIFY® STEAM Value Indicators are process indicators that undergo a visual color change when exposed to steam in a temperature range of 121°C to 135°C (250°F to 275°F).

5. DEVICE DESCRIPTION

Similar to the parent Modified Browne Packaging and Label Steam Process Indicator, the proposed VERIFY® STEAM Value Indicators consists of indicator ink applied to a suitable substrate, i.e. packaging material, self-adhesive labels, tapes, tags, inserts, etc. Modifications to the parent indicator to produce the proposed VERIFY® STEAM Value Indicators included changes to the indicator ink composition, modification to the process used for application of the indicator ink to the substrates, and minor changes to the suite of compatible substrates. The modifications to the indicator ink composition were made to produce two variants with different color change schemes and improve the "printability" of the ink.

6. TECHNOLOGICAL CHARACTERISTICS

Both the proposed and predicate devices consist of indicator ink applied to a substrate. The indicator ink changes color to confirm exposure to steam. The substrates used to support the indicator ink are similar for the proposed and predicate devices. Changes were made to the indicator ink formulation to produce two different color change schemes and improve the "printability" of the ink. However, the chemical reaction that induces the indicator ink to change color is identical for the parent and proposed indicators.

7. PERFORMANCE TESTING

Albert Browne Ltd. has performed testing which demonstrates that the VERIFY® STEAM Value Indicators conform to the applicable requirements of ANSI/AAMI ST60 for Class I process indicators for steam sterilization. Additional testing confirmed that the indicators performed as designed under in use conditions using all of the compatible substrates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 7 2006

Albert Browne Limited
C/O Ms. Cynthia J.M. Nolte
Medical Device Consultants
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K060103
Trade/Device Name: Albert Browne Limited VERIFY® STEAM Value Indicators
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization process indicator
Regulatory Class: II
Product Code: JOJ
Dated: February 27, 2006
Received: March 1, 2006

Dear Ms. Nolte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

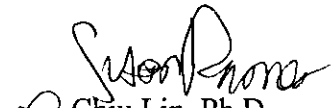
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital ,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060103

Device Name: Albert Browne Ltd. VERIFY® STEAM Value Indicators

Indications for Use:

The Albert Browne Ltd. VERIFY® STEAM Value Indicators are process indicators that undergo a visual color change when exposed to steam in a temperature range of 121°C to 135°C (250°F to 275°F).

Prescription Use _____ AND/OR Over-The-Counter Use __x__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheila R. Murphy 3/7/06

Microbiology, General Hospital
Ophthalmic and Dental Devices

K060103